

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF MISSISSIPPI
DELTA DIVISION

FRANCES ROBERTSON and
TIM ROBERTSON

Plaintiffs

v.

MERCK & CO., INC.

Defendant

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Case No.: 2:07CV027-M-A

JURY TRIAL DEMANDED

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ANSWER AND DEFENSES TO COMPLAINT

Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

PARTIES

1. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of Paragraph 1.

2. Merck denies each and every allegation of Paragraph 2, except Merck admits that it is a New Jersey corporation and has its principal place of business located at One Merck Drive, Whitehouse Station, New Jersey and admits that it is registered to do business in New York and Mississippi.

JURISDICTION AND VENUE

The allegations of the first sentence of this section are conclusions of law to which no response is required. To the extent that a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of

the first sentence of this section. As to the allegations of the second sentence of this section, Merck states that, for jurisdictional purposes only, it admits that the Plaintiffs seek in excess of \$75,000. Merck denies each and every allegation of the third sentence of this section. The allegations of the fourth sentence of this section are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of the fourth sentence of this section.

Nature of the Case

Merck denies each and every allegation of this section, except Merck admits that Plaintiffs purport to bring this action for damages, but denies that there is any legal or factual basis for same.

Facts

1. Merck denies each and every allegation of Paragraph 1, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX®.
2. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 2 inconsistent with that prescribing information. Merck respectfully refers the Court to the Physician's Desk Reference ("PDR") for FOSAMAX® for its actual language and full text.
3. Merck denies each and every allegation of Paragraph 3, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing

information. Merck denies any allegations in Paragraph 3 inconsistent with that prescribing information.

4. Merck denies each and every allegation of Paragraph 4.

5. Merck denies each and every allegation of Paragraph 5.

6. Merck denies each and every allegation of Paragraph 6, except that it admits that Ruggiero, et al., published an article entitled, "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004) and respectfully refers the Court to said article for its actual language and full text.

7. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 7.

8. Merck denies each and every allegation of Paragraph 8.

9. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 9.

10. Merck denies each and every allegation of Paragraph 10.

11. Merck denies each and every allegation of Paragraph 11, including each and every allegation contained in subparts (a) – (g).

Legal Theories and Causes of Action

Merck denies each and every allegation of this section, except to the extent specifically admitted below:.

FIRST: Merck denies each and every allegation of the "FIRST" part of this section.

SECOND: Merck denies each and every allegation of the “SECOND” part of this section.

THIRD: Merck denies each and every allegation of the “THIRD” part of this section, except Merck states that the allegations of the third sentence of in this part state a legal conclusion to which no response is required. To the extent a response is required, Merck denies each and every allegation of the third sentence of this part and respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

FOURTH: Merck denies each and every allegation of the “FOURTH” part of this section, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

PRAYER FOR RELIEF

Merck denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs’ Complaint with prejudice and awarding Merck its reasonable attorney’s fees, together with such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these

affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®,

such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were cause in whole or in part by the contributory negligence of the allegedly injured Plaintiffs.

EIGHTH AFFIRMATIVE DEFENSE

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault.

NINTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiffs knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs rely upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recovery for strict liability because Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiffs' claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and Mississippi Constitutions.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available

medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs have not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs have not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claimed are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

FORTIETH AFFIRMATIVE DEFENSE

Merck affirmatively pleads Miss. Code § 85-5-7 (1972), as amended by Miss. Laws 2003, 3rd Ex. Sess., Ch. 2 § 4, effective January 1, 2003.

FORTY-FIRST AFFIRMATIVE DEFENSE

To the extent that Plaintiffs' claims are based upon any theory of product liability, they are barred or limited by Mississippi's Product Liability Act, Miss. Code § 11-1-63 (1972), as amended by Miss. Laws 2004, 1st Ex. Sess., Ch. 1 § 3, effective September 1, 2004.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claim for non-economic damages are subject to and limited by Miss. Code § 11-1-60 (1) (a) through (c) (1972), as amended by Miss. Laws 2004, 1st Ex. Sess., Ch. 1 § 2, effective September 1, 2004.

FORTY-THIRD AFFIRMATIVE DEFENSE

Should Merck be held liable to Plaintiffs, which liability is specifically denied, Merck would be entitled to a set off for the total of all amounts paid to Plaintiffs from all collateral sources.

FORTY-FORTH AFFIRMATIVE DEFENSE

Some or all of the damages alleged by Plaintiffs are barred by Miss. Code §§ 75-2-714, 715 (1972).

FORTY-FIFTH AFFIRMATIVE DEFENSE

Notwithstanding the claims and contentions of Plaintiff, she received all or substantially all of the benefit from Fosamax that she hoped and intended to receive, and, to that extent, any damages and/or restitution that Plaintiffs might be entitled to recover from Merck must be correspondingly reduced.

FORTY-SIXTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under the applicable state law.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claim for any punitive damages against Merck fails under Miss. Code § 11-1-65 (1972), as amended by Miss. Laws 2004, 1st Ex. Sess., Ch. 1 § 4, effective September 1, 2004.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations, and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution and the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of

its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing the Complaint with prejudice and awarding Merck its reasonable costs and disbursements, including reasonable attorneys' fees, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

Respectfully submitted,

s/ Alyson B. Jones
CHRISTY D. JONES, (MS #3192)
ALYSON JONES (MS #101456)

ATTORNEYS FOR
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CERTIFICATE OF SERVICE

I hereby certify that on April 13, 2007, I electronically filed the foregoing with the Clerk of the Court using the ECF system which sent notification to the following ECF participants:

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ATTORNEY FOR THE PLAINTIFFS

SO CERTIFIED this the 13th day April, 2007.

s/ Alyson B. Jones
ALYSON B. JONES

Jackson 2015310v.1